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May 23, 2024

VIA ECF

The Honorable Leda D. Wettre, U.S.M.J.
United States District Court
Martin Luther King, Jr. Federal Building
50 Walnut Street, Room 2060
Newark, New Jersey 07102

Re: *Axsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*
Civil Action No. 23-1695 (MEF)(LDW) (consolidated)

Dear Judge Wettre:

This firm, together with Quinn Emanuel, represents Plaintiffs Axsome Therapeutics, Inc. and Antecip Bioventures II LLC (together, “Plaintiffs”) in this case. We write on behalf of all parties to provide a status update prior to the May 30, 2024 teleconference pursuant to Your Honor’s February 23, 2024 Order Consolidating Cases for All Purposes (ECF No. 52).

In accordance with Your Honor’s Consolidation Order, on April 11, 2024, Defendant Teva Pharmaceuticals, Inc. (“Teva”) served its non-infringement and invalidity contentions for certain 2043-expiring patents. Plaintiffs are diligently working on providing their responses by the June 17, 2024 deadline. The parties will then begin exchanging *Markman* disclosures on June 28, 2024. The only pending item currently before Your Honor is Teva’s March 8, 2024 request for leave to amend its L. Pat. R. 3.6(c) invalidity contentions relating to a different group of patents (which Plaintiffs opposed). *See* ECF No. 54.

The parties are actively engaged in fact discovery, with both sides having served and responded to multiple rounds of discovery requests. While the parties have been meeting and conferring about the appropriate scope of discovery, the disputes are not yet ripe. If the parties reach an impasse on any of these issues, we will raise it promptly with the Court.

In letters dated April 10, 2024 and May 1, 2024, Teva notified Plaintiffs that Teva’s ANDA No. 218147 “seeks approval to engage in the commercial manufacture, use, or sale of” Teva’s ANDA Product “prior to expiration of” five additional patents that are listed in the Orange Book for Auvelity®. Accordingly, based on Teva’s representation, and while there is no 30-month statutory stay for these patents, Plaintiffs intend to file a complaint asserting patent

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infringement of these five patents against Teva.¹ We will be prepared to discuss this with Your Honor during next week's status conference.

Teva's Position:

A few discovery issues may require the Court's attention soon. Teva served its First Set of Requests for Production nine months ago, on August 25, 2023. Plaintiffs have not yet agreed to produce, or search for, responsive documents. The parties have attempted to resolve these issues, including exchanging significant written correspondence and conducting lengthy meet-and-confer teleconferences, including local counsel. As of today, Teva still has no firm commitment from Plaintiffs that they will produce responsive documents. In contrast, Teva has conducted searches to confirm whether documents responsive to Plaintiffs' First Set of RFPs exist. Teva has informed Plaintiffs when no such documents exist, has produced laboratory notebooks regarding the development of Teva's ANDA Product, and is in the process of producing financial documents.

In addition, Plaintiffs note that they will soon be filing suit on five newly-issued patents. It is Teva's position that these new patents should not delay the current case.

Plaintiffs' Position:

As Teva acknowledges, the parties are attempting to resolve their disagreements without the need for burdening the Court. In fact, Plaintiffs have similar concerns about the status of Teva's production—Plaintiffs similarly served their First Set of Requests for Production nine months ago, on August 21, 2023, and to date, Teva has produced little more than what is required under the Local Patent Rules. However, Plaintiffs remain optimistic that the parties can reach agreement regarding the appropriate scopes of production in the near future.

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,

s/ Liza M. Walsh

Liza M. Walsh
Counsel for Defendant

Respectfully yours,

s/ Charles M. Lizza

Charles M. Lizza
Counsel for Plaintiffs

cc: All counsel of record (via email)

¹ The Orange Book lists approximately 100 other patents that Plaintiffs contend cover Auvelity[®] and methods of using Auvelity[®] that are not the subject of this litigation. The latest expiring of those patents are set to expire on November 5, 2034. Accordingly, the FDA cannot approve Teva's ANDA until at least November 5, 2034.